Remarks

Claims 27 to 42 are pending. Favorable consideration is respectfully requested.

The Applicant wishes to extend his appreciation to Examiner's Rex Holmes and George Evanisko for timely scheduling a conference call telephone interview, and for the courtesy extended to Applicants attorney during the interview on October 15, 2007. At the interview, Applicant's attorney briefly summarized the present invention, which is directed to a portable device which allows a patient to ascertain his/her risk of atrial fibrillation independently (without the assistance of a physician), and without having special training to facilitate a subjective evaluation. The device measures successive RR intervals, creates a virtual scatter plot from these intervals, and compares the virtual scatter plot with a virtual scatter plot of normal heart activity. The comparison allows the generation of a small number of fixed value signals, which correspond respectively to increasing risk of atrial fibrillation. The state signals are essentially on/off signals which activate respective visible displays. In a preferred embodiment, for example, four LED displays represent, respectively, (1) substantially no risk of atrial fibrillation; (2) low risk; (3) moderate risk; and (4) high risk. It is equally possible to use a three LED display, to where no LED is illuminated for a no risk condition. Likewise, it is possible for alternative individual displays such as those discussed in the specification to be used. Examples include a LCD unit having a "pie chart" configuration, with each of four sectors of the "pie" respectively corresponding to a risk state signal. The state signals are fixed value signals, not continuous variables. For example, the state signals could be represented by a two digit binary code: 00, 01, 10, 11. Such a signal determines which individual display or displays will be illuminated.

The Examiners reviewed proposed claims submitted and made several recommendations regarding claim amendments to clarify the scope of the claims and to patentably distinguish over the art. While no final language was agreed upon, it was agreed that claims incorporating the principles discussed would be patentable over the art of record.

A discussion of the reference teachings also took place. It was agreed that none of the references taught or suggested creating fixed value state signals as claimed. Some comments on the art are presented below.

Gilham is the principle reference. *Gilham* teaches the use of scatter plots, preferably colored scatter plots, to identify heart abnormalities, by displaying the scatter plots on a monitor screen, allowing the cardiac specialist to determine whether an abnormal pattern is present. However, *Gilham* does not disclose any process of characterizing relative risks of any particular abnormality. Rather, the diagnostic method proposed by *Gilham* is for identifying a particular type of abnormality from among recognized types such as sinus rhythm with ectopic beats, atrial flutter, atrial fibrillation, heart block, wandering atrial parameter, and the like. *Gilham* does not teach further analyzing data to determine a degree of risk, and his method is intended for use by personnel trained in heart diagnostics and scatter plots, preferably also in connection with other data such as ECG (electrocardiogram) data. As *Gilham* states in column 15, the technique is designed "to verify the presence or absence of the detected rhythmic condition." Thus, *Gilham* is not directed to quantifying degrees of risk, only whether a particular type of abnormality is present or not.

In column 16, *Gilham* discloses two quantifying measures employing scatter plot comparisons. In the first (line 18 and following), the difference in area of a patient's scatter plot and a normal scatter plot is disclosed. However, this value is a continuous variable, not a state signal.

Moreover, as can be seen from these scatter plot examples, this value alone cannot determine risk, since both "healthy" and "non-healthy" scatter plots can have areas which are larger or smaller than the normal plot. Thus, the principle purpose of this measurement appears to be to alert the physician to the fact that there is a difference, and hence him/her decide whether the difference is a good or bad thing.

At line 25 and following, an aspect ratio is measured. This measurement, again, is a continuous variable, and not a small set of predetermined state signals. Its use is to track changes in the heart condition over periods of time. It is clearly not a state signal.

Kamen also uses scatter plots to quantify heart activity, but does not teach or suggest generating a state signal. *Kamen*, like *Gilham* is directed to an apparatus for use by physicians in diagnosis. *Kamen* teaches the use of a "correlation dimension" which is described in column 6, line 34 and following. The correlation dimension is a smoothed continuous variable in which the standard deviation of the differences between successive RR intervals (ΔRR) or the root mean square of these deviations is measured. In any case, again, this is a continuous variable, and not a state signal. *Kamen*, like *Gilham*, used these values to differentiate signal. Different types of heart abnormalities, not differing degrees of a single abnormality.

Levitan was familiar with the"correlation dimension" proposed by *Kamen*, and in column 2, disparages the use of *Kamen's* method. For this reason, Applicant's attorney suggested during the interview that the combination of *Kamen* with *Levitan* might be inappropriate. *Levitan*, like *Gilham*, uses scatter plots to identify a particular type of abnormality from among a number of types. See, e.g., column 3, lines 10-52. This method involves calculating a matrix determinant of the matrix product of the respective quadrupole moments of the data points in the plot relative to the X and Y axes. Depending on the determinant value, which again is a continuous variable, patients are sorted into groups associated with their risk of heart failure. It is noted that this "sorting" procedure is among patients, and it does not single out a specific patient and then determine whether his current risk factor is, for example, low, moderate or high. Moreover, and most importantly, unlike *Gilham* and also unlike *Kamen*, *Levitan* does not compare a patient's scatter plot with a normal scatter plot. Actually, in column 2, this is what *Levitan* counsels against doing. Rather, *Levitan* uses only the patient's scatter plot and generates a quadrupole determinant from it. *Levitan* thus teaches away from the claimed invention which compares normal and patient scatter plots.

Owen is not seen as being particularly relevant, as it pertains to a defibrillator, and not to heart diagnostics. Like virtually all medical equipment, the defibrillator has a display where text messages can be displayed, and LED's for indicating different operational states. However, there is no disclosure or suggestion of state signals related to degrees of atrial fibrillation.

The claims have been amended consistent with Applicant's attorney's understanding of the principles discussed during the interview. All the claim amendments are believed to be fully supported by the application as filed. If the Examiner believes further clarification is required, he is highly encouraged to telephone Applicants attorney.

Respectfully submitted,

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Date: Oct. 22, 2007

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